EVALUATION OF MICRODOT+ IN A CLINICAL SETTING

A patient user performance evaluation study was carried out by an independent third party at the Staploe Medical Centre, Cambridgeshire, U.K over a period of approximately six weeks from 13 May 2010 to 22 June 2010. The study protocol was reviewed and approved by the Cambridge Local Research Ethics Committee. Each participant signed an informed consent form prior to being enrolled in the study.

Design of the Study

This comprehensive independent third party evaluation compared blood glucose results obtained by the patient with capillary whole blood from a fingerstick with results obtained at the same time by a Healthcare Professional (HCP) with capillary whole blood from a fingerstick only. A separate sample was collected by the HCP from the fingerstick and tested on a YSI 2300 laboratory Analyzer to obtain a plasma calibrated result. The meter results were compared with the results obtained on the YSI 2300 Analyzer. The sample hematocrit was also measured to ensure that only patients that were within the acceptance range for the meter system were included in the study.

Patients were selected at random to provide a broad range of age, gender and mix of educational levels of typical subjects doing home blood glucose monitoring. The ethnic background of the subjects was also recorded.

Study participants were required to review the user guide and instruction sheets. After the review they are asked to perform a "use test" with control solution. Using only the product labelling as reference, the patient performed blood glucose testing with the microdot +® System on their finger for comparison with the HCP testing on the finger with the microdot +® System. Using a second puncture from the patient immediately after their test, the HCP performs a test on the microdot® +System. Finally a sample of blood from the same fingerstick is collected for the additional tests on the laboratory instrument, the YSI 2300 analyzer and hematocrit measuring instrument.

Results

100% of the results from both finger tests by Subject and HCP were within the ISO 15197:2003 accuracy criteria of ± 15 mg/dL bias for glucose samples ≤ 75 mg/dL. 98% of the results from the Finger tests by the HCP were within the ISO 15197:2003 accuracy criteria of ± 20% bias for glucose samples > 75 mg/dL and 97% of finger test results by the subject were within the ISO 15197:2003 accuracy criteria of ± 20% bias for glucose samples > 75 mg/dL.